DEC 13 2013

5. 510(K) SUMMARY

Submitter's Name:	Genesys Spine
Submitter's Address:	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746
Submitter's Telephone:	512-381-7080
Submitter's Fax:	800-817-4938
Contact Name:	William W. Sowers
Date Summary was Prepared:	1-Apr-13
Trade or Proprietary Name:	Genesys Spine Apache™ Lateral Lumbar Interbody Fusion System
Common or Usual Name:	Intervertebral Fusion Device, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Codes:	MAX
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Legally Marketed (unmodified) device:	Genesys Spine Apache™ Interbody Fusion System, Lumbar (K103034)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Genesys Spine Apache™ Lateral Lumbar Interbody Fusion System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of a Genesys Spine lumbar interbody fusion device, which may be implanted as a single device via a lateral approach.

INDICATIONS FOR USE

The Genesys Spine Apache™ Lateral Lumbar Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

TECHNICAL CHARACTERISTICS

The Genesys Spine Apache™ Lateral Lumbar Interbody Fusion System is comprised of various device configurations designed to accommodate patient anatomy and provide the surgeon with different surgical approach options.

The Genesys Spine Interbody Fusion System implant components are made of polyether ether ketone (Invibio PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device. The additional implant offering being proposed has similar technological characteristics and identical indications as the currently cleared product line.

PERFORMANCE DATA

Not Required. FEA analysis and projected area calculations show that a new worst-case device was not created. This analysis tool was validated (calibrated) by the predicate system's mechanical test data and is sufficient to allow for a substantial equivalence designation for the subject device. In addition, the length, width, and height of the Lateral Lumbar Interbody Fusion System implants fall within the scope of devices already cleared per K103034.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that Genesys Spine Apache™ Lateral Lumbar Interbody Fusion System is substantially equivalent to the Genesys Spine Apache™ Lumbar Interbody System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 13, 2013

Genesys Spine
Mr. William W. Sowers
Vice President of Quality and Regulatory
1250 Capital of Texas Highway South, Building Three, Suite 600
Austin, Texas 78746

Re: K130913
Trade/Device Name: Genesys Spine Apache™ Lateral Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: November 14, 2013
Received: November 15, 2013

Dear Mr. Sowers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Device Name: Genesys Spine Apache™ Lateral Lumbar Interbody Fusion System

The Genesys Spine Apache™ Lateral Lumbar Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices